HOUSE BILL 2567

By Casada

AN ACT to amend Tennessee Code Annotated, Title 53, relative to opioid analgesic drugs.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 53, Chapter 10, is amended by adding Sections 2 through 4 as a new Part 5 thereto.

SECTION 2. As used in this part, unless the context otherwise requires:

(1) “Interchange or substitution of an opioid analgesic drug” means the substitution of any opioid analgesic drug, brand or generic, for an opioid analgesic drug incorporating a tamper-resistance technology originally prescribed, irrespective of whether the substituted drug is rated as pharmaceutically and therapeutically equivalent by the United States food and drug administration (USFDA) or board of pharmacy or whether the opioid analgesic drug with tamper-resistance technology bears a labeling claim with respect to reduction of tampering, abuse or abuse potential;

(2) “Opioid analgesic drug” means a drug in the opioid analgesic drug class prescribed to treat moderate to severe pain or other conditions, whether in immediate release or extended release form and whether or not combined with other drug substances to form a single tablet or other dosage form;

(3) “Opioid analgesic drug incorporating a tamper resistance technology” means an opioid analgesic drug listed as such by the board of pharmacy based upon a submission of evidence by the drug manufacturer or distributor that the drug incorporates a tamper resistance technology and has been approved by the USFDA pursuant to an application that includes at least one human tampering or abuse potential study or a laboratory study comparing the tamper- or abuse resistance properties of the

drug to one (1) or more opioid analgesic drugs that have been approved by the USFDA; and serve as a positive control; and

(4) “Pharmacist” means any pharmacist dispensing drugs under the jurisdiction of the board of pharmacy.

SECTION 3. The board of pharmacy shall publish a list of opioid analgesic drugs incorporating tamper resistance technology. Inclusion of a drug on such list shall not require that a drug bear a labeling claim with respect to reduction of tampering, abuse or abuse potential at the time of listing. Such list shall also include a determination by the board of pharmacy as to which listed opioid analgesic drugs incorporating tamper resistance technologies provide substantially similar tamper-resistance properties, based solely upon studies submitted by the drug manufacturer.

SECTION 4. Notwithstanding chapter 10, part 2 of this title, no pharmacist shall interchange or substitute an opioid analgesic drug, brand or generic, that is otherwise eligible for such interchange or substitution under chapter 10, part 2 of this title, for an opioid analgesic drug incorporating a tamper resistance technology without:

(1) Verifying that the opioid analgesic drug has been listed by the board of pharmacy as providing tamper resistance properties substantially similar to the prescribed opioid analgesic drug incorporating a tamper resistance technology; or

(2) Obtaining written, signed consent from the prescribing physician for such interchange or substitution.

SECTION 5. This act shall take effect July 1, 2012, the public welfare requiring it.